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| APPLICATION NO.                          | FILING DATE | FIRST NAMED INVENTOR    | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|-------------------------|---------------------|------------------|
| 10/762,616                               | 01/22/2004  | Luisa Hernandez-Ramirez | 91349               | 5023             |
| 24628                                    | 7590        | 03/16/2010              |                     | EXAMINER         |
| Husch Blackwell Sanders, LLP             |             |                         |                     | SIMMONS, CHRIS E |
| Husch Blackwell Sanders LLP Welsh & Katz |             |                         |                     |                  |
| 120 S RIVERSIDE PLAZA                    |             |                         | ART UNIT            | PAPER NUMBER     |
| 22ND FLOOR                               |             |                         | 1612                |                  |
| CHICAGO, IL. 60606                       |             |                         |                     |                  |
|  |             |                         | MAIL DATE           | DELIVERY MODE    |
|  |             |                         | 03/16/2010          | PAPER            |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

|                              |                                      |   |
|------------------------------|--------------------------------------|---|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/762,616 | <b>Applicant(s)</b><br>HERNANDEZ-RAMIREZ ET AL. |
|                              | <b>Examiner</b><br>CHRIS E. SIMMONS  | <b>Art Unit</b><br>1612                         |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 03 November 2009.  
 2a) This action is FINAL.      2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-3,5,6,13 and 15-22 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-3,5,6,13 and 15-22 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO/SB/06)  
     Paper No(s)/Mail Date \_\_\_\_\_
- 4) Interview Summary (PTO-413)  
     Paper No(s)/Mail Date \_\_\_\_\_  
 5) Notice of Informal Patent Application  
 6) Other: \_\_\_\_\_

**DETAILED ACTION**

Applicants' arguments, filed 11/03/2009, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

***Claim Rejections - 35 USC § 103***

Claims 1, 13, 15, 17, 19 and 21 stand rejected under 35 U.S.C. 103(a) as being unpatentable over US 2003/0130225 in view of Wallin et al. (Br. J. Vener. Dis. (1974);50;148-150).

Applicant argues that neither reference teaches the amounts claimed and further notes that both references tout the efficacy of using 2 grams tinidazole and secnidazole in a unit dosage. Examiner does not find these arguments persuasive. Despite any alleged touting of the efficacy of using 2 grams of secnidazole or tinidazole, the secondary reference also discloses that less than 2 grams are effective. Touting one embodiment does not dissuade from practicing other embodiments.

Applicant further asserts that the size of the tablet has been minimized by both references through the use of more tablets, which would minimize the motivation to minimize the size. Examiner notes that the primary reference discloses the medicament may be administered in *one or more* doses. It further discloses the problems with patient compliance due to prolonged regimens

Art Unit: 1612

[0013]. If the tablet is administered in a single dose, then the size of the tablet would not have been minimized through the use of multiple tablets as alleged by applicant. Accordingly, the artisan would then be motivated to minimize the amounts of ingredient in the tablets to minimize the size of a single tablet to be administered in a single dose as disclosed in the reference.

Applicant argues that there is no motivation to combine tinidazole with another treatment to reach the desired results because the secondary reference did not suggest that any more is needed in terms of treatment since the four tablets of 500mg of tinidazole gave best results. Applicant notes, however, that the primary reference suggests that something additional is needed when treatment with oral fluconazole is administered. At page 2 of the response, applicant states:

"Thus, a reasonable conclusion [from the primary reference] would be that, at the time, the oral administration of fluconazole was not considered sufficient for complete treatment of the condition. It is apparent, then, that something in addition to simply the oral administration of fluconazole was necessary. Applicant has filled this need by the additional oral application of less than two grams of tinidazole."

Examiner contends that the apparent need for something in addition to oral fluconazole would motivate the skilled artisan to seek to fill this need with the use of oral tinidazole since the secondary reference discloses that 2g or less is a sufficient amount for treatment. A disclosure that a certain treatment regimen can effectively treat a disease does not dissuade the artisan from the natural desire to improve upon what is already known. Examiner notes further that the successful treatment of a disease does not teach away from modifying the

Art Unit: 1612

treatment. Accordingly, applicant's argument that the secondary reference's disclosure that 4 doses of 500mg of tinidazole gave the best results is not found to be persuasive.

Applicant argues that the motivation to select tinidazole from the list of 71 drugs from [0058] of the primary reference is lacking since this list does not provide the skilled artisan with a finite number of identified predictable solutions. Applicant also notes that "timidazole" is listed in the long list of compounds and not "tinidazole". Examiner notes that the rejection is not based on selecting from this group of compounds. Instead it is based on combining the disclosure of fluconazole in the primary reference with the disclosure of tinidazole in the secondary reference. Examiner notes that "timidazole" in [0058] is a typographical error for "tinidazole".

Claims 2, 3, 5, 18, 20, and 22 stand rejected under 35 U.S.C. 103(a) as being unpatentable over US 2003/0130225 in view of Videau et al. (Br. J. Vener. Dis. (1978);54;77-80).

Applicant relies on the above arguments to overcome this rejection. Examiner does not find these arguments to be persuasive for reasons set forth above.

Art Unit: 1612

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 2003/0130225 and Videau et al., the combination taken in view of USP 5,660,860.

Applicant relies on the above arguments to overcome this rejection. Examiner does not find these arguments to be persuasive for reasons set forth above.

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 2003/0130225 and Wallin et al., the combination taken further in view of USP 5,660,860.

Applicant relies on the above arguments to overcome this rejection. Examiner does not find these arguments to be persuasive for reasons set forth above.

No claims allowed.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory

Art Unit: 1612

period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRIS E. SIMMONS whose telephone number is (571)272-9065. The examiner can normally be reached on Monday - Friday from 7:30 - 5:00 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service

Art Unit: 1612

Representative or access to the automated information system, call 800-786-

9199 (IN USA OR CANADA) or 571-272-1000.

/C. E. S./

Examiner, Art Unit 1612

/Frederick Krass/

Supervisory Patent Examiner, Art Unit 1612